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### **CLAIMS**

# [Claim(s)]

[Claim 1]A balloon which will be contracted if said fluid is discharged while extending, if a fluid is supplied to an inside, When a lumen which the distal end side is joined to this balloon, penetrates from the proximal edge side to the distal end side, and is open for free passage inside said balloon extends a tube used as a feeding-and-discarding way of said fluid, and said balloon, the balloon concerned a blood vessel in a position suppressed from the outside. A cardiac performance auxiliary device provided with a holder which can hold this balloon. [Claim 2]A cardiac performance auxiliary device, wherein said balloon is being fixed from this holder to said holder in the cardiac performance auxiliary device according to claim 1 so that desorption is possible.

[Claim 3]A cardiac performance auxiliary device characterized by fixing said balloon inside this annular solid with structure where said holder forms an annular solid with which a form surrounding a periphery of a blood vessel can be equipped in the cardiac performance auxiliary device according to claim 1 or 2.

[Claim 4]A cardiac performance auxiliary device which adjusting the inside diameter arbitrarily and comprising a fixable fixing means in the cardiac performance auxiliary device according to claim 3 when said holder twists a flexible band form and this band form around a periphery of a blood vessel.

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# DETAILED DESCRIPTION

[Detailed Description of the Invention] [0001]

[Field of the Invention] This invention relates blood-pressure assistance to a feasible cardiac performance auxiliary device by applying a pressure from the outside of a blood vessel. [0002]

[Description of the Prior Art]In order to assist with a patient's cardiac function conventionally, IABP (intraaortic balloon pumping) which is one of the assisted circulation is carried out widely in the medical site. This IABP is the method of inserting a balloon catheter into a blood vessel from a patient's femoral artery etc., deriving the balloon at a tip in a main artery, detaining it, and performing blood-pressure assistance for a balloon extension and by making it contracting (pumping) to compensate for the pulsation of the heart.

[0003]

[Problem(s) to be Solved by the Invention]By the way, although the above IABP(s) may be carried out also to the patient on whom a thoracotomy operation is conducted, Since a crack had to be given also to the insertion part of a balloon catheter and bleeding would also be generated with insertion of a balloon catheter in addition to a patient's thorax if IABP is carried out in parallel to a thoracotomy operation, the burden accompanying operation of IABP had been placed on the patient in addition to the burden accompanying a thoracotomy operation. [0004]As a general problem in IABP, besides the above, generating of obstacles, such as formation of a thrombus, hemolysis, a burst of a balloon, and an interruption in the circulation of the membrum inferius, is pointed out, and the development of assisted circulation which does not concur with such an obstacle was expected. this invention is made in order to solve the above-mentioned problem, and it comes out. The purpose is to provide a feasible cardiac performance auxiliary device about blood-pressure assistance by applying a pressure from the outside of a blood vessel, without inserting inside.

# [0005]

[The means for solving a technical problem and an effect of the invention] In order to attain the above-mentioned purpose, the cardiac performance auxiliary device according to claim 1, The balloon which will be contracted if said fluid is discharged while extending, if a fluid is supplied to an inside, When the lumen which the distal end side is joined to this balloon, penetrates from the proximal edge side to the distal end side, and is open for free passage inside said balloon extends the tube used as the feeding-and-discarding way of said fluid, and said balloon, the balloon concerned a blood vessel in the position suppressed from the outside. It had the holder which can hold this balloon.

[0006]If according to this cardiac performance auxiliary device it arranges on the outside of a blood vessel, the balloon is held with the holder in that state and a fluid is supplied in a balloon via a tube, Since a balloon will contract and the pressure to a blood vessel will be loosened if a balloon is extended, a blood vessel is pressed from the outside, and it continues and the fluid in a balloon is discharged via a tube, While an intravascular pressure can be heightened at the time of extension of a balloon, an intravascular pressure can be lowered at the time of contraction of a balloon.

[0007]Therefore, if it is a case where the operations to which a main artery can be exposed, such as a thoracotomy operation, are conducted, for example, the same blood-pressure assistance as the case of IABP can be performed by arranging a balloon so that a main artery may be pressed, doubling with the pulsation of the heart, and extending and shrinking a balloon. By arranging a balloon so that an ascending aorta may be pressed, and more specifically extending a balloon at the diastole of the heart, for example in the case of a thoracotomy operation, Raise the blood pressure in an ascending aorta, increase the blood stream to a coronary artery, can supply more oxygen to a myocardium, and, on the other hand, by making the contraction stage of the heart contract a balloon, The blood pressure in an ascending aorta is lowered, by the negative pressure effect, sending-out resistance of the blood from the left ventricle to a main artery can be reduced, and work of the left ventricle can be reduced.

[0008]If it is such a cardiac performance auxiliary device, in carrying out to a patient on whom a thoracotomy operation etc. are conducted, a crack is given in addition to a patient's thorax, \*\*\*\*\*\*\*\* also becomes good, excessive bleeding is also prevented and a patient's burden becomes light rather than a case where IABP is used together. A problem produced by inserting a balloon catheter into a blood vessel in IABP since the outside of a blood vessel is equipped with the above-mentioned cardiac performance auxiliary device, That is, since it will not result in mixing of driving fluid into a blood vessel even if it does not generate and a problem of an interruption in the circulation of formation of a thrombus, hemolysis, and

membrum inferius, etc. causes a burst of a balloon, there is almost no adverse effect to a patient.

[0009]Although a gas or a fluid can be considered as the above-mentioned fluid, with a point excellent in a response, a small gas of flow resistance is desirable and it is possible to use gaseous helium for which IABP is also used. However, since there are no worries of a break through of gas into a blood vessel like IABP, gases other than gaseous helium can also be used broadly.

[0010]Although a balloon and a tube should just be formed with the same material as a balloon catheter for IABP, since this is not inserted into a blood vessel, either, It also becomes possible especially of height of anti-thrombus nature or insertion nature for it not to be required, to be able to choose a suitable material out of more material, for example, to think endurance etc. as important, and to choose material. About a holder, if it has the rigidity of a grade whose fabricating operation is an easy resin material and which will not be limited especially if this is also the material which does not have an adverse effect in a human body, and it does not transform very easily, it is [ anything ] good.

[0011]In order to drive this cardiac performance auxiliary device, what is necessary is just to have connected to the proximal edge side of a tube a drive which carries out the feeding and discarding of the fluid synchronizing with pulsation of the heart, and the proximal edge side of a tube may be equipped with a connector for exclusive use etc. Since a drive will carry out the feeding and discarding of the fluid synchronizing with pulsation of the heart if it carries out like this, a balloon of a cardiac performance auxiliary device can be driven good, and expected auxiliary circulation can be carried out. Such a drive should just be constituted completely like a drive used in IABP.

[0012] By the way, although after an end of a thoracotomy operation usually continues blood-pressure assistance using the above-mentioned cardiac performance auxiliary device in many cases, if a thoracotomy operation is again conducted in order to remove this cardiac performance auxiliary device in that case, a patient's burden will increase. To such a problem, to said holder, as for the cardiac performance auxiliary device according to claim 2, said balloon is being fixed from this holder so that desorption is possible.

[0013]Extraction only of a balloon and the tube can be carried out to the outside of the body, leaving only a holder to the inside of the body by desorbing a balloon from a holder, when it was this cardiac performance auxiliary device and a cardiac performance auxiliary device is removed. Therefore, in order to remove a cardiac performance auxiliary device, it is not necessary to conduct a thoracotomy operation again, and a patient's burden does not increase.

[0014]About a method of fixing a balloon from a holder, so that desorption is possible. . Although not limited in particular, paste up a holder and a balloon with adhesive strength of a

grade which can desorb a balloon from a holder easily only by pulling a tube, for example. Or what is necessary is just to say that a joining section of a balloon and a holder is cut, if a wire or thread etc. which it let pass in a tube is pulled. Although left behind to the inside of the body about a holder, it is only detained in the outside of the blood vessel, and a problem which becomes especially a patient's burden is not produced.

[0015]If a balloon can be held in a position in which a balloon presses a blood vessel in the outside of a blood vessel about concrete shape of a holder at the time of extension of a balloon, Although not limited in particular, with structure which forms an annular solid with which the form according to claim 3 in which said holder surrounds a periphery of a blood vessel like can be equipped, for example. Since a holder will not drop out of a blood vessel and a blood vessel which is inside the same annular solid will moreover be pressed in connection with a balloon being extended by the inside of an annular solid if said balloon is being fixed inside this annular solid, pressure of a blood vessel is certainly repeatable. [0016]When it equips so that a blood vessel may be surrounded from both sides of a blood vessel, such a holder should just be the structure used as an annular solid, and specifically, For example, a thing which will serve as an annular solid if U character shaped part article of another side is attached to one U character shaped part article, Or although an annular solid etc. which were arbitrarily constituted by connecting U character shaped part article of a couple by a thin-walled part formed in the shape of a hinge so that ring breakage was possible may be what kind of structure, like the cardiac performance auxiliary device according to claim 4, If the inside diameter is adjusted arbitrarily and it comprises a fixable fixing means when said holder twists a flexible band form and this band form around a periphery of a blood vessel, In equipping a periphery of a blood vessel with a holder, Since it can twist so that a flexible band form may be stuck on a periphery of a blood vessel, and it can fix using a fixing means in the position, even when an outer diameter of a blood vessel changes with patients, a size can be adjusted by the holder side and it can equip properly to a patient.

[0017]By adjusting an inside diameter of a band form arbitrarily, if the above-mentioned fixing means is fixable, Although not limited in particular, when giving a concrete example, for example a face fastener constituted a part or all of a band form and a band form is twisted around a periphery of a blood vessel, the inside diameter is adjusted arbitrarily and it can fix. A buckle part by which one end of a band form lets the other end of a band form pass is formed, Even if it constitutes so that a nail which formed an annular solid in this buckle part through the other end of a band form, and was formed in a buckle part may be caught in either of two or more holes installed successively by longitudinal direction of a band form, when a band form is twisted around a periphery of a blood vessel, that inside diameter is adjusted arbitrarily and it can fix.

[0018]

[Embodiment of the Invention]Next, the embodiment of this invention is described based on Drawings. As shown in <u>drawing 1</u>, the cardiac performance auxiliary device 1 is the shape surrounding the balloon 10 which is a bag-like object made from polyurethane, the tube 12 made from polyurethane with which the balloon 10 was joined to the distal end side, and the periphery of the balloon 10, A part of inner skin is equipped with the holder 14 made from an acrylic which a part of periphery of the balloon 10 pasted up, and the connector 20 is formed in the proximal edge side of the tube 12.

[0019]The yne deflation port 22 used as a gas supplying port is established in the connector 20, and inside the connector 20, The gas passageway which is open for free passage from the yne deflation port 22 to the lumen of the tube 12 is formed, and the lumen of this tube 12 is further open for free passage inside the balloon 10 by the distal end side of the tube 12. If gas is supplied from the yne deflation port 22, the gas will be supplied to the balloon 10 via the tube 12, and the balloon 10 will be extended. If gas is made to discharge from the yne deflation port 22, negative pressure will start the lumen of the tube 12, and the inside of the balloon 10, and the balloon 10 will contract.

[0020]The stainless lines 24 are arranged in the state of penetrating the inside of the balloon 10, and the lumen of the tube 12. As for these stainless lines 24, in one end, the other end has adhered [tip side of the balloon 10] to the inside of the connector 20, respectively. Such stainless lines 24 are functioning also as a reinforcing member when the role which prevents bending in the part of the tube 12 etc. is played and the tube 12 is pulled.

[0021]If the above-mentioned holder 14 has the lid 26 of a sliding type, is made into the structure which serves as an annular solid where the lid 26 is attached and makes this lid 26 slide to a graphic display arrow direction as shown in <u>drawing 2</u>, it can remove and carry out ring breakage of the lid 26 which makes a part of ring. The hole 28 can open in the lid 26, this hole 28 lets the thread 30 pass, as shown in <u>drawing 1</u>, and it is tied with the tube 12. The lid 26 is pressed fit to the holder 14, and unless power is made to apply and slide intentionally, it does not separate.

[0022]The lid 26 is the part P which serves as an opposite hand on both sides of the balloon 10, and the balloon 10 and the holder 14 are mutually pasted up, as shown in <u>drawing 3</u> (a). Therefore, if the balloon 10 is shrunk while the balloon 10 will spread inside [ whole ] the holder 14 mostly as shown in <u>drawing 3</u> (a) if the balloon 10 is extended, as shown in <u>drawing 3</u> (b), The balloon 10 contracts in the form where it gathered to the direction of the adhesion part P, and a big crevice arises between the balloon 10 and the lid 26.

[0023]Therefore, if the balloon 10 is shrunk beforehand, it can arrange so that the lid 26 may be removed and it may let a blood vessel pass in the above-mentioned crevice, and will become a form where the holder 14 surrounds the periphery of a blood vessel, by attaching the lid 26 again. Next, the directions for this cardiac performance auxiliary device 1 are

explained.

[0024]When conducting a thoracotomy operation, for example and a patient's blood pressure fell is caused, or when it is expected that a blood pressure fell is caused, as shown in <u>drawing 4 (a)</u>, the ascending aorta 50 is equipped with the cardiac performance auxiliary device 1. At the time of wearing, it changes the balloon 10 into the state where it contracted, and the crevice between the balloon 10 and the holder 14 lets the ascending aorta 50 pass as abovementioned.

[0025]And to compensate for the pulsation of the heart, the balloon 10 drives by carrying out the feeding and discarding of the gaseous helium etc. from the connector 20 side. Since the drive which drives the balloon 10 in this way is completely the same as the drive used in IABP etc., explanation here is omitted.

[0026]If the drive of the balloon 10 is started, as extended \*\* also of the balloon 10 is carried out at the diastole of the heart and it is shown in drawing 4 (b), the ascending aorta 50 will be pressed from the outside, the blood pressure in the inside will be raised, and the blood stream to the coronary artery 52 will be increased. Thereby more much oxygen is supplied to a myocardium. As the balloon 10 is also shrunk at the contraction stage of the heart and it is shown in drawing 4 (a) on the other hand, the pressure to the ascending aorta 50 is loosened and the blood pressure in the inside is lowered. As a result, sending-out resistance of the blood from the left ventricle 54 to the ascending aorta 50 falls, and work of the left ventricle 54 is reduced by the negative pressure effect.

[0027]In this way, a thoracotomy operation is finished, carrying out auxiliary circulation. Although a patient's breast is closed by the end of a thoracotomy operation, since about one to two weeks after the operation needs to continue the auxiliary circulation by the cardiac performance auxiliary device 1, generally the cardiac performance auxiliary device 1 is detained in a patient's inside of the body.

[0028]Then, if a patient's condition is recovered, extraction of the cardiac performance auxiliary device 1 will be carried out. The balloon 10, the tube 12, etc. are drawn out from a patient's inside of the body, leaving the holder 14 to a patient's inside of the body at this time. The adhesive strength of the holder 14 and the balloon 10 is intensity which is a grade from which the balloon 10 will separate from the holder 14 if the tube 12 is pulled, and the holder 14 and the balloon 10 can be separated easily. The holder 14 does not have an adverse effect on a human body, and even if detained in the inside of the body, a problem does not have it. [0029]Thus, since a crack is given in addition to a patient's thorax, \*\*\*\*\*\*\*\*\*\*\* also becomes good and excessive bleeding is also prevented when carrying out auxiliary circulation to the patient on whom a thoracotomy operation etc. are conducted according to the cardiac performance auxiliary device 1, a patient's burden becomes light rather than the case where IABP is used together.

[0030]The problem produced by inserting a balloon catheter into a blood vessel in IABP since the outside of a blood vessel is equipped with the cardiac performance auxiliary device 1, That is, since it will not result in mixing of the driving fluid into a blood vessel even if it does not generate and the problem of the interruption in the circulation of formation of a thrombus, hemolysis, and the membrum inferius, etc. causes the burst of the balloon 10, there is almost no adverse effect to a patient.

[0031]As mentioned above, although the embodiment of this invention was described, about the constituent means of this invention, many things are considered besides the abovementioned embodiment. For example, the holder 14 of the above-mentioned cardiac performance auxiliary device 1 may serve as shape which is tinged with the radius of circle which cannot damage a blood vessel more easily, although outside diameter shape had become a rectangular parallelepiped.

[0032]It is not limited in particular for concrete shape, such as a thing with which a lid and a holder make mutual unevenness engage, and a thing with which the lid and the holder are connected via the hinge, although it explained that the lid 26 was pressed fit in the holder 14. A holder is not restricted to what forms an annular solid united with a lid as mentioned above. As shown in drawing 5 (a) - the figure (c), the holder 40 more specifically, for example The flexible band form 41, When it constitutes from the buckle part 43 provided in one end of the band form 41 and lets the other end of the band form 41 pass to the buckle part 43, it is good also as a structure where the band form 41 coils around the periphery of the balloon 45 and the ascending aorta 50 by becoming annular. In this holder 40, the engaging projection 47 protrudes inside the buckle part 43, If the engaging projection 47 is inserted in the engaging hole 49 in a suitable position on the other hand after many engaging holes' 49 being installed successively by the band form 41 at a longitudinal direction and letting the band form 41 pass to the buckle part 43, the holder 40 is fixable in the state where it twisted around the periphery of the ascending aorta 50. Since the inside diameter of the ring which the band form 41 forms can be changed according to the bundle condition of the band form 41 if it is such a holder 40, even if the outer diameter of the ascending aorta 50 changes by a patient, it can equip appropriately.

[0033]If the face fastener constitutes the above-mentioned band form 41, even if it does not form the buckle part 43, it can be made annular and can fix in a suitable position.

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# **TECHNICAL FIELD**

[Field of the Invention] This invention relates blood-pressure assistance to a feasible cardiac performance auxiliary device by applying a pressure from the outside of a blood vessel.

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# **PRIOR ART**

[Description of the Prior Art]In order to assist with a patient's cardiac function conventionally, IABP (intraaortic balloon pumping) which is one of the assisted circulation is carried out widely in the medical site. This IABP is the method of inserting a balloon catheter into a blood vessel from a patient's femoral artery etc., deriving the balloon at a tip in a main artery, detaining it, and performing blood-pressure assistance for a balloon extension and by making it contracting (pumping) to compensate for the pulsation of the heart.

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# EFFECT OF THE INVENTION

[The means for solving a technical problem and an effect of the invention] In order to attain the above-mentioned purpose, the cardiac performance auxiliary device according to claim 1 will be extended if a fluid is supplied to an inside.

The balloon which will be contracted on the other hand if said fluid is discharged, and the tube with which the lumen which the distal end side is joined to this balloon, penetrates from the proximal edge side to the distal end side, and is open for free passage inside said balloon serves as a feeding-and-discarding way of said fluid, When said balloon was extended, the balloon concerned was provided with the holder which can hold this balloon in the position which presses a blood vessel from the outside.

[0006]If according to this cardiac performance auxiliary device it arranges on the outside of a blood vessel, the balloon is held with the holder in that state and a fluid is supplied in a balloon via a tube, Since a balloon will contract and the pressure to a blood vessel will be loosened if a balloon is extended, a blood vessel is pressed from the outside, and it continues and the fluid in a balloon is discharged via a tube, While an intravascular pressure can be heightened at the time of extension of a balloon, an intravascular pressure can be lowered at the time of contraction of a balloon.

[0007]Therefore, if it is a case where the operations to which a main artery can be exposed, such as a thoracotomy operation, are conducted, for example, the same blood-pressure assistance as the case of IABP can be performed by arranging a balloon so that a main artery may be pressed, doubling with the pulsation of the heart, and extending and shrinking a balloon. By arranging a balloon so that an ascending aorta may be pressed, and more specifically extending a balloon at the diastole of the heart, for example in the case of a thoracotomy operation, Raise the blood pressure in an ascending aorta, increase the blood stream to a coronary artery, can supply more oxygen to a myocardium, and, on the other hand,

by making the contraction stage of the heart contract a balloon, The blood pressure in an ascending aorta is lowered, by the negative pressure effect, sending-out resistance of the blood from the left ventricle to a main artery can be reduced, and work of the left ventricle can be reduced.

[0008]If it is such a cardiac performance auxiliary device, in carrying out to a patient on whom a thoracotomy operation etc. are conducted, a crack is given in addition to a patient's thorax, \*\*\*\*\*\*\*\*\* also becomes good, excessive bleeding is also prevented and a patient's burden becomes light rather than a case where IABP is used together. A problem produced by inserting a balloon catheter into a blood vessel in IABP since the outside of a blood vessel is equipped with the above-mentioned cardiac performance auxiliary device, That is, since it will not result in mixing of driving fluid into a blood vessel even if it does not generate and a problem of an interruption in the circulation of formation of a thrombus, hemolysis, and membrum inferius, etc. causes a burst of a balloon, there is almost no adverse effect to a patient.

[0009]Although a gas or a fluid can be considered as the above-mentioned fluid, with a point excellent in a response, a small gas of flow resistance is desirable and it is possible to use gaseous helium for which IABP is also used. However, since there are no worries of a break through of gas into a blood vessel like IABP, gases other than gaseous helium can also be used broadly.

[0010]Although a balloon and a tube should just be formed with the same material as a balloon catheter for IABP, since this is not inserted into a blood vessel, either, It also becomes possible especially of height of anti-thrombus nature or insertion nature for it not to be required, to be able to choose a suitable material out of more material, for example, to think endurance etc. as important, and to choose material. About a holder, if it has the rigidity of a grade whose fabricating operation is an easy resin material and which will not be limited especially if this is also the material which does not have an adverse effect in a human body, and it does not transform very easily, it is [ anything ] good.

[0011]In order to drive this cardiac performance auxiliary device, what is necessary is just to have connected to the proximal edge side of a tube a drive which carries out the feeding and discarding of the fluid synchronizing with pulsation of the heart, and the proximal edge side of a tube may be equipped with a connector for exclusive use etc. Since a drive will carry out the feeding and discarding of the fluid synchronizing with pulsation of the heart if it carries out like this, a balloon of a cardiac performance auxiliary device can be driven good, and expected auxiliary circulation can be carried out. Such a drive should just be constituted completely like a drive used in IABP.

[0012] By the way, although after an end of a thoracotomy operation usually continues blood-pressure assistance using the above-mentioned cardiac performance auxiliary device in many

cases, if a thoracotomy operation is again conducted in order to remove this cardiac performance auxiliary device in that case, a patient's burden will increase. To such a problem, to said holder, as for the cardiac performance auxiliary device according to claim 2, said balloon is being fixed from this holder so that desorption is possible.

[0013]Extraction only of a balloon and the tube can be carried out to the outside of the body, leaving only a holder to the inside of the body by desorbing a balloon from a holder, when it was this cardiac performance auxiliary device and a cardiac performance auxiliary device is removed. Therefore, in order to remove a cardiac performance auxiliary device, it is not necessary to conduct a thoracotomy operation again, and a patient's burden does not increase.

[0014]About a method of fixing a balloon from a holder, so that desorption is possible. . Although not limited in particular, paste up a holder and a balloon with adhesive strength of a grade which can desorb a balloon from a holder easily only by pulling a tube, for example. Or what is necessary is just to say that a joining section of a balloon and a holder is cut, if a wire or thread etc. which it let pass in a tube is pulled. Although left behind to the inside of the body about a holder, it is only detained in the outside of the blood vessel, and a problem which becomes especially a patient's burden is not produced.

[0015]If a balloon can be held in a position in which a balloon presses a blood vessel in the outside of a blood vessel about concrete shape of a holder at the time of extension of a balloon, Although not limited in particular, with structure which forms an annular solid with which the form according to claim 3 in which said holder surrounds a periphery of a blood vessel like can be equipped, for example. Since a holder will not drop out of a blood vessel and a blood vessel which is inside the same annular solid will moreover be pressed in connection with a balloon being extended by the inside of an annular solid if said balloon is being fixed inside this annular solid, pressure of a blood vessel is certainly repeatable. [0016]When it equips so that a blood vessel may be surrounded from both sides of a blood vessel, such a holder should just be the structure used as an annular solid, and specifically, For example, a thing which will serve as an annular solid if U character shaped part article of another side is attached to one U character shaped part article, Or although an annular solid etc. which were arbitrarily constituted by connecting U character shaped part article of a couple by a thin-walled part formed in the shape of a hinge so that ring breakage was possible may be what kind of structure, like the cardiac performance auxiliary device according to claim 4, If the inside diameter is adjusted arbitrarily and it comprises a fixable fixing means when said holder twists a flexible band form and this band form around a periphery of a blood vessel, In equipping a periphery of a blood vessel with a holder, Since it can twist so that a flexible band form may be stuck on a periphery of a blood vessel, and it can fix using a fixing means in the position, even when an outer diameter of a blood vessel changes with patients, a size can be

adjusted by the holder side and it can equip properly to a patient.

[0017]By adjusting an inside diameter of a band form arbitrarily, if the above-mentioned fixing means is fixable, Although not limited in particular, when giving a concrete example, for example a face fastener constituted a part or all of a band form and a band form is twisted around a periphery of a blood vessel, the inside diameter is adjusted arbitrarily and it can fix. A buckle part by which one end of a band form lets the other end of a band form pass is formed, Even if it constitutes so that a nail which formed an annular solid in this buckle part through the other end of a band form, and was formed in a buckle part may be caught in either of two or more holes installed successively by longitudinal direction of a band form, when a band form is twisted around a periphery of a blood vessel, that inside diameter is adjusted arbitrarily and it can fix.

[0018]

[Embodiment of the Invention]Next, the embodiment of this invention is described based on Drawings. As shown in <u>drawing 1</u>, the cardiac performance auxiliary device 1 is the shape surrounding the balloon 10 which is a bag-like object made from polyurethane, the tube 12 made from polyurethane with which the balloon 10 was joined to the distal end side, and the periphery of the balloon 10, A part of inner skin is equipped with the holder 14 made from an acrylic which a part of periphery of the balloon 10 pasted up, and the connector 20 is formed in the proximal edge side of the tube 12.

[0019]The yne deflation port 22 used as a gas supplying port is established in the connector 20, and inside the connector 20, The gas passageway which is open for free passage from the yne deflation port 22 to the lumen of the tube 12 is formed, and the lumen of this tube 12 is further open for free passage inside the balloon 10 by the distal end side of the tube 12. If gas is supplied from the yne deflation port 22, the gas will be supplied to the balloon 10 via the tube 12, and the balloon 10 will be extended. If gas is made to discharge from the yne deflation port 22, negative pressure will start the lumen of the tube 12, and the inside of the balloon 10, and the balloon 10 will contract.

[0020]The stainless lines 24 are arranged in the state of penetrating the inside of the balloon 10, and the lumen of the tube 12. As for these stainless lines 24, in one end, the other end has adhered [tip side of the balloon 10] to the inside of the connector 20, respectively. Such stainless lines 24 are functioning also as a reinforcing member when the role which prevents bending in the part of the tube 12 etc. is played and the tube 12 is pulled.

[0021]If the above-mentioned holder 14 has the lid 26 of a sliding type, is made into the structure which serves as an annular solid where the lid 26 is attached and makes this lid 26 slide to a graphic display arrow direction as shown in <u>drawing 2</u>, it can remove and carry out ring breakage of the lid 26 which makes a part of ring. The hole 28 can open in the lid 26, this hole 28 lets the thread 30 pass, as shown in drawing 1, and it is tied with the tube 12. The lid

26 is pressed fit to the holder 14, and unless power is made to apply and slide intentionally, it does not separate.

[0022]The lid 26 is the part P which serves as an opposite hand on both sides of the balloon 10, and the balloon 10 and the holder 14 are mutually pasted up, as shown in <u>drawing 3</u> (a). Therefore, if the balloon 10 is shrunk while the balloon 10 will spread inside [ whole ] the holder 14 mostly as shown in <u>drawing 3</u> (a) if the balloon 10 is extended, as shown in <u>drawing 3</u> (b), The balloon 10 contracts in the form where it gathered to the direction of the adhesion part P, and a big crevice arises between the balloon 10 and the lid 26.

[0023] Therefore, if the balloon 10 is shrunk beforehand, it can arrange so that the lid 26 may be removed and it may let a blood vessel pass in the above-mentioned crevice, and will become a form where the holder 14 surrounds the periphery of a blood vessel, by attaching the lid 26 again. Next, the directions for this cardiac performance auxiliary device 1 are explained.

[0024]When conducting a thoracotomy operation, for example and a patient's blood pressure fell is caused, or when it is expected that a blood pressure fell is caused, as shown in <u>drawing 4 (a)</u>, the ascending aorta 50 is equipped with the cardiac performance auxiliary device 1. At the time of wearing, it changes the balloon 10 into the state where it contracted, and the crevice between the balloon 10 and the holder 14 lets the ascending aorta 50 pass as abovementioned.

[0025]And to compensate for the pulsation of the heart, the balloon 10 drives by carrying out the feeding and discarding of the gaseous helium etc. from the connector 20 side. Since the drive which drives the balloon 10 in this way is completely the same as the drive used in IABP etc., explanation here is omitted.

[0026]If the drive of the balloon 10 is started, as extended \*\* also of the balloon 10 is carried out at the diastole of the heart and it is shown in drawing 4 (b), the ascending aorta 50 will be pressed from the outside, the blood pressure in the inside will be raised, and the blood stream to the coronary artery 52 will be increased. Thereby more much oxygen is supplied to a myocardium. As the balloon 10 is also shrunk at the contraction stage of the heart and it is shown in drawing 4 (a) on the other hand, the pressure to the ascending aorta 50 is loosened and the blood pressure in the inside is lowered. As a result, sending-out resistance of the blood from the left ventricle 54 to the ascending aorta 50 falls, and work of the left ventricle 54 is reduced by the negative pressure effect.

[0027]In this way, a thoracotomy operation is finished, carrying out auxiliary circulation. Although a patient's breast is closed by the end of a thoracotomy operation, since about one to two weeks after the operation needs to continue the auxiliary circulation by the cardiac performance auxiliary device 1, generally the cardiac performance auxiliary device 1 is detained in a patient's inside of the body.

[0028]Then, if a patient's condition is recovered, extraction of the cardiac performance auxiliary device 1 will be carried out. The balloon 10, the tube 12, etc. are drawn out from a patient's inside of the body, leaving the holder 14 to a patient's inside of the body at this time. The adhesive strength of the holder 14 and the balloon 10 is intensity which is a grade from which the balloon 10 will separate from the holder 14 if the tube 12 is pulled, and the holder 14 and the balloon 10 can be separated easily. The holder 14 does not have an adverse effect on a human body, and even if detained in the inside of the body, a problem does not have it. [0029]Thus, since a crack is given in addition to a patient's thorax, \*\*\*\*\*\*\*\*\*\*\* also becomes good and excessive bleeding is also prevented when carrying out auxiliary circulation to the patient on whom a thoracotomy operation etc. are conducted according to the cardiac performance auxiliary device 1, a patient's burden becomes light rather than the case where IABP is used together.

[0030]The problem produced by inserting a balloon catheter into a blood vessel in IABP since the outside of a blood vessel is equipped with the cardiac performance auxiliary device 1, That is, since it will not result in mixing of the driving fluid into a blood vessel even if it does not generate and the problem of the interruption in the circulation of formation of a thrombus, hemolysis, and the membrum inferius, etc. causes the burst of the balloon 10, there is almost no adverse effect to a patient.

[0031]As mentioned above, although the embodiment of this invention was described, about the constituent means of this invention, many things are considered besides the above-mentioned embodiment. For example, the holder 14 of the above-mentioned cardiac performance auxiliary device 1 may serve as shape which is tinged with the radius of circle which cannot damage a blood vessel more easily, although outside diameter shape had become a rectangular parallelepiped.

[0032]It is not limited in particular for concrete shape, such as a thing with which a lid and a holder make mutual unevenness engage, and a thing with which the lid and the holder are connected via the hinge, although it explained that the lid 26 was pressed fit in the holder 14. A holder is not restricted to what forms an annular solid united with a lid as mentioned above. As shown in drawing 5 (a) - the figure (c), the holder 40 more specifically, for example The flexible band form 41, When it constitutes from the buckle part 43 provided in one end of the band form 41 and lets the other end of the band form 41 pass to the buckle part 43, it is good also as a structure where the band form 41 coils around the periphery of the balloon 45 and the ascending aorta 50 by becoming annular. In this holder 40, the engaging projection 47 protrudes inside the buckle part 43, If the engaging projection 47 is inserted in the engaging hole 49 in a suitable position on the other hand after many engaging holes' 49 being installed successively by the band form 41 at a longitudinal direction and letting the band form 41 pass to the buckle part 43, the holder 40 is fixable in the state where it twisted around the periphery

of the ascending aorta 50. Since the inside diameter of the ring which the band form 41 forms can be changed according to the bundle condition of the band form 41 if it is such a holder 40, even if the outer diameter of the ascending aorta 50 changes by a patient, it can equip appropriately.

[0033]If the face fastener constitutes the above-mentioned band form 41, even if it does not form the buckle part 43, it can be made annular and can fix in a suitable position.

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# TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]By the way, although the above IABP(s) may be carried out also to the patient on whom a thoracotomy operation is conducted, Since a crack had to be given also to the insertion part of a balloon catheter and bleeding would also be generated with insertion of a balloon catheter in addition to a patient's thorax if IABP is carried out in parallel to a thoracotomy operation, the burden accompanying operation of IABP had been placed on the patient in addition to the burden accompanying a thoracotomy operation. [0004]As a general problem in IABP, besides the above, generating of obstacles, such as formation of a thrombus, hemolysis, a burst of a balloon, and an interruption in the circulation of the membrum inferius, is pointed out, and the development of assisted circulation which does not concur with such an obstacle was expected. this invention is made in order to solve the above-mentioned problem, and it comes out. The purpose is to provide a feasible cardiac performance auxiliary device about blood-pressure assistance by applying a pressure from the outside of a blood vessel, without inserting inside.

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# DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]It is a side view of the cardiac performance auxiliary device shown as an example of an embodiment.

[Drawing 2]It is a perspective view of a holder part.

[Drawing 3]It is the cutting plane end elevation shown in drawing 1 by the A-A line, and the state to which (a) extended the balloon, and the state where (b) shrank the balloon are shown, respectively.

[Drawing 4]It is a mimetic diagram showing the condition of use of a cardiac performance auxiliary device, and (a) shows the state of the contraction stage of the heart and (b) shows the state of the diastole of the heart, respectively.

[Drawing 5] It is the cardiac performance auxiliary device shown as another example of an embodiment, and, as for the perspective view and (b), the sectional view and (c) of (a) are the expanded sectional views near a buckle part.

[Description of Notations]

1 ... A cardiac performance auxiliary device, 10 ... A balloon, 12 ... Tube, 14 ... A holder, 20 ... A connector, 22 ... Yne deflation port, 24 [ ... Thread, 40 / ... A holder, 41 / ... A band form, 43 / ... A buckle part, 45 / ... A balloon, 47 / ... An engaging projection, 49 / ... Engaging hole. ] ... Stainless lines, 26 ... A lid, 28 ... A hole, 30

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(71)出願人 392013143

株式会社ヴァーユ

愛知県名古屋市東区徳川町611番地

(72)発明者 四津 良平

神奈川県横浜市港北区篠原町1526-18

(72)発明者 三丸 敦洋

東京都新宿区市谷木村町5-2-204

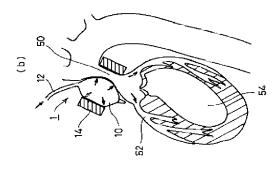
(74)代理人 弁理士 足立 勉

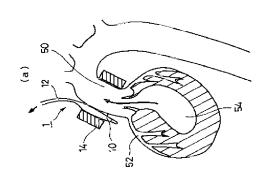
### (54) 【発明の名称】 心機能補助装置

### (57)【要約】

【課題】 血管内へ挿入することなく、血管の外側から 圧力を加えることによって血圧補助を実施可能な心機能 補助装置を提供すること。

【解決手段】 心機能補助装置1は、バルーン10、チ ューブ12、ホルダ14を備え、心臓の拡張期にバルー ン10を拡張することにより、上行大動脈50を外側か ら圧迫し、その内部における血圧を高め、冠動脈52へ の血流量を増大させる(図(b))。心臓の収縮期には バルーン10を収縮させ、上行大動脈50に対する圧迫 を緩め、その内部における血圧を低め、陰圧効果によっ て左心室54から上行大動脈50への血液の送出抵抗を 低下させ、左心室54の仕事を軽減する(図(a))。 患者の容態が回復してくれば、心機能補助装置1が抜去 される。この時は、ホルダ14を患者の体内に残したま ま、バルーン10およびチューブ12などが患者の体内 から引き抜かれる。





### 【特許請求の範囲】

【請求項1】 内部へ流体を供給すると拡張する一方、 前記流体を排出すると収縮するバルーンと、

該バルーンに遠位端側が接合され、近位端側から遠位端側へ貫通して前記バルーンの内部に連通する内腔が前記 流体の給排路となるチューブと、

前記バルーンを拡張した際に当該バルーンが血管を外側から圧迫する位置で、該バルーンを保持可能なホルダとを備えたことを特徴とする心機能補助装置。

【請求項2】 請求項1記載の心機能補助装置において、

前記バルーンが、前記ホルダに対し該ホルダから脱着可能に固定されていることを特徴とする心機能補助装置。

【請求項3】 請求項1または請求項2記載の心機能補助装置において、

前記ホルダが、血管の外周を囲む形に装着可能な環状体 を形成する構造で、該環状体の内側に前記バルーンが固 定されていることを特徴とする心機能補助装置。

【請求項4】 請求項3記載の心機能補助装置において、

前記ホルダが、柔軟な帯状体と、該帯状体を血管の外周 に巻き付けた際に、その内径を任意に調整して固定可能 な固定手段とで構成されていることを特徴とする心機能 補助装置。

### 【発明の詳細な説明】

# [0001]

【発明の属する技術分野】本発明は、血管の外側から圧力を加えることによって血圧補助を実施可能な心機能補助装置に関する。

### [0002]

【従来の技術】従来、患者の心臓機能を補助するために、補助循環法の一つである IABP (大動脈内バルーンパンピング)が、広く医療現場で実施されている。この IABPは、バルーンカテーテルを患者の大腿動脈等から血管内に挿入して、先端のバルーンを大動脈内まで誘導して留置し、バルーンを心臓の拍動に合わせて拡張および収縮(パンピング)させることにより、血圧補助を行う方法である。

# [0003]

【発明が解決しようとする課題】ところで、上述のようなIABPは、開胸手術が行われる患者に対しても実施される場合があるが、開胸手術に並行してIABPを実施すると、患者の胸部以外に、バルーンカテーテルの挿入箇所にも傷をつけなければならず、バルーンカテーテルの挿入に伴って出血も発生するため、患者には開胸手術に伴う負担以外に、IABPの実施に伴う負担がかかっていた。

【0004】また、IABPにおける一般的な問題としては、上記の他にも、血栓の形成、溶血、バルーンの破裂、下肢の血行障害などといった障害の発生が指摘され

ており、こうした障害を併発しない補助循環法の開発が 期待されていた。本発明は、上記問題を解決するために なされたものであり、その目的は、血管内へ挿入するこ となく、血管の外側から圧力を加えることによって血圧 補助を実施可能な心機能補助装置を提供することにあ る。

#### [0005]

【課題を解決するための手段、および発明の効果】上述の目的を達成するために、請求項1記載の心機能補助装置は、内部へ流体を供給すると拡張する一方、前記流体を排出すると収縮するバルーンと、該バルーンに遠位端側が接合され、近位端側から遠位端側へ貫通して前記バルーンの内部に連通する内腔が前記流体の給排路となるチューブと、前記バルーンを拡張した際に当該バルーンが血管を外側から圧迫する位置で、該バルーンを保持可能なホルダとを備えたことを特徴とする。

【0006】この心機能補助装置によれば、血管の外側に配置して、その状態でバルーンをホルダによって保持しておき、チューブを介してバルーン内に流体を供給すると、バルーンが拡張して血管を外側から圧迫し、また続いて、チューブを介してバルーン内の流体を排出すると、バルーンが収縮して血管への圧迫を緩めるので、バルーンの拡張時には血管内の圧力を高めることができる一方、バルーンの収縮時には血管内の圧力を低めることができる。

【0007】したがって、例えば開胸手術など、大動脈を露出させることのできる手術を行う場合であれば、大動脈を圧迫するようにバルーンを配置して、心臓の拍動に合わせてバルーンを拡張および収縮させることにより、IABPの場合と同様の血圧補助を行うことができる。より具体的には、例えば開胸手術の際に、上行大動脈を圧迫するようにバルーンを配置して、心臓の拡張期にバルーンを拡張することにより、上行大動脈内における血圧を高め、冠動脈への血流量を増大させてより多くの酸素を心筋に供給することができ、一方、心臓の収縮期にバルーンを収縮させることにより、上行大動脈内における血圧を低め、陰圧効果によって左心室から大動脈への血液の送出抵抗を低下させて、左心室の仕事を軽減することができる。

【0008】このような心機能補助装置であれば、開胸手術等が行われる患者に対して実施する場合には、患者の胸部以外に傷をつけなけくてもよくなり、余計な出血も防止され、IABPを併用する場合よりも患者の負担が軽くなる。また、上記心機能補助装置は、血管の外側に装着されるので、IABPにおいてバルーンカテーテルを血管内へ挿入することによって生じる問題、すなわち、血栓の形成、溶血、下肢の血行障害などといった問題は発生せず、また、仮にバルーンの破裂を招いたとしても、血管内への駆動流体の混入には至らないので、患者に対する悪影響はほとんどない。

【0009】なお、上記流体としては、気体又は液体を考えることができるが、応答性に優れている点では流動抵抗の小さい気体が望ましく、IABPなどでも利用されるヘリウムガスを用いることが考えられる。但し、IABPのような血管内へのガスの漏出といった心配がないので、ヘリウムガス以外の気体でも幅広く利用することができる。

【0010】また、バルーンおよびチューブは、IAB P用バルーンカテーテルと同様の材料で形成されていればよいが、これも血管内へは挿入されないので、抗血栓性や挿入性の高さは特に要求されず、より多くの材料の中から好適な材料を選択することができ、例えば耐久性等を重視して材料を選択するといったことも可能となる。ホルダについては、これも人体に悪影響のない材料であれば特に限定されず、成形加工が容易な樹脂材料で、きわめて容易には変形しない程度の剛性を備えたものであれば何でもよい。

【0011】また、この心機能補助装置を駆動するに は、心臓の拍動に同期して流体を給排する駆動装置を、 チューブの近位端側に接続すればよく、チューブの近位 端側には専用のコネクタ等を備えていてもよい。こうす れば、駆動装置が心臓の拍動に同期して流体を給排する ので、心機能補助装置のバルーンを良好に駆動すること ができ、所期の補助循環を実施することができる。な お、このような駆動装置は、IABPにおいて使用され る駆動装置と全く同様に構成されたものであればよい。 【0012】ところで、開胸手術の終了後も、通常は上 記心機能補助装置を使って血圧補助を続けることが多い が、その場合、この心機能補助装置を取り外すために再 び開胸手術を行うのでは、患者の負担が増大してしま う。このような問題に対し、請求項2記載の心機能補助 装置は、前記バルーンが、前記ホルダに対し該ホルダか ら脱着可能に固定されていることを特徴とする。

【0013】この心機能補助装置であれば、心機能補助装置を取り外す際には、バルーンをホルダから脱着することにより、ホルダだけを体内に残したまま、バルーンおよびチューブだけを体外へ抜去することができる。したがって、心機能補助装置を取り外すために再び開胸手術を行う必要がなく、患者の負担が増大することはない。

【0014】バルーンをホルダから脱着可能に固定する方法については、特に限定されないが、例えば、チューブを引っ張るだけで容易にホルダからバルーンを脱着できる程度の接着強度でホルダとバルーンを接着しておく、あるいはチューブ内に通されたワイヤ又は糸等を引っ張るとバルーンとホルダとの接合部分が切断されるといったものであればよい。なお、ホルダについては体内に残されることになるが、血管外に留置されるだけであり、特に患者の負担になるような問題は生じない。

【0015】また、ホルダの具体的な形状については、

血管の外側においてバルーンの拡張時にバルーンが血管を圧迫する位置にバルーンを保持することができれば、特に限定されないが、例えば請求項3記載のように、前記ホルダが、血管の外周を囲む形に装着可能な環状体を形成する構造で、該環状体の内側に前記バルーンが固定されていれば、血管からホルダが脱落するようなことがなく、しかも、環状体の内側でバルーンが拡張するのに伴って、同じ環状体の内側にある血管は圧迫されることになるので、確実に血管の圧迫を繰り返すことができる。

【0016】このようなホルダは、血管の両側から血管 を取り囲むように装着すると環状体となる構造であれば よく、具体的には、例えば一方のU字状部品に他方のU 字状部品を取り付けると環状体となるもの、あるいは一 対のU字状部品がヒンジ状に形成された薄肉部で連結さ れることにより任意に開環可能に構成された環状体な ど、どのような構造であってもよいが、請求項4記載の 心機能補助装置のように、前記ホルダが、柔軟な帯状体 と、該帯状体を血管の外周に巻き付けた際に、その内径 を任意に調整して固定可能な固定手段とで構成されてい ると、ホルダを血管の外周に装着するに当たっては、柔 軟な帯状体を血管の外周に密着させるように巻き付け て、その位置で固定手段を使って固定することができる ので、患者によって血管の外径が異なる場合でも、ホル ダ側で寸法を調整して、患者に対して適正に装着するこ とができる。

【0017】なお、上記固定手段は、帯状体の内径を任意に調整して固定可能であれば、特に限定されるものではないが、具体的な例を挙げれば、例えば、帯状体の一部または全部を面ファスナによって構成すれば、帯状体を血管の外周に巻き付けた際に、その内径を任意に調整して固定できる。また、帯状体の一端に帯状体の他端が通されるバックル部を形成して、このバックル部に帯状体の他端を通して環状体を形成するようにし、バックル部に形成した爪が帯状体の長手方向に列設された複数の穴のいずれかに引っかかるように構成しても、帯状体を血管の外周に巻き付けた際に、その内径を任意に調整して固定できる。

# [0018]

【発明の実施の形態】次に、本発明の実施形態を図面に基づいて説明する。図1に示すように、心機能補助装置1は、ポリウレタン製の袋状体であるバルーン10と、バルーン10が遠位端側に接合されたポリウレタン製のチューブ12と、バルーン10の外周を囲む形状で、内周面の一部にバルーン10の外周の一部が接着されたアクリル製のホルダ14とを備え、チューブ12の近位端側にはコネクタ20が設けられている。

【0019】コネクタ20には、ガス供給口となるインデフレーションポート22が設けられ、コネクタ20の内部には、インデフレーションポート22からチューブ

12の内腔へと連通するガス流路が形成され、更にこのチューブ12の内腔は、チューブ12の遠位端側でバルーン10の内部に連通している。インデフレーションポート22からガスを供給すると、そのガスがチューブ12を介してバルーン10に供給されてバルーン10が拡張する。また、インデフレーションポート22からガスを排出させると、チューブ12の内腔およびバルーン10の内部に陰圧がかかってバルーン10が収縮する。

【0020】また、バルーン10の内部およびチューブ12の内腔を貫通する状態で、ステンレス線24が配置されている。このステンレス線24は、一端がバルーン10の先端側、他端がコネクタ20の内部にそれぞれ固着されている。このようなステンレス線24は、チューブ12の局所における折れ曲がりなどを防止する役割を果たし、また、チューブ12が引っ張られた場合の補強材としても機能している。

【0021】更に、上記ホルダ14は、図2に示すように、スライド式の蓋26を有し、蓋26を取り付けた状態で環状体となる構造とされ、この蓋26を、図示矢印方向へスライドさせると、環の一部をなす蓋26を取り外して開環することができる。また、蓋26には穴28が開けられ、この穴28には、図1に示すように糸30が通されてチューブ12につなぎ止められている。なお、蓋26は、ホルダ14に対して圧入されるもので、意図的に力を加えてスライドさせない限り外れることはない。

【0022】また、バルーン10とホルダ14は、図3 (a)に示すように、蓋26とはバルーン10を挟んで反対側となる箇所Pで、互いに接着されている。そのため、バルーン10を拡張すると、図3(a)に示すように、バルーン10がほぼホルダ14の内側全体に広がる一方、バルーン10を収縮させると、図3(b)に示すように、バルーン10が接着箇所Pの方に寄り集まった形で収縮し、バルーン10と蓋26との間に大きな隙間が生じる。

【0023】したがって、バルーン10をあらかじめ収縮させておけば、蓋26を取り外して上記隙間に血管を通すように配置することができ、再び蓋26を取り付けることにより、ホルダ14が血管の外周を囲む形になる。次に、この心機能補助装置1の使用方法について説明する。

【0024】心機能補助装置1は、例えば開胸手術を行う際に、患者の血圧低下を招いた場合、あるいは血圧低下を招くと予想される場合に、図4(a)に示すように、上行大動脈50に装着される。装着時には、バルーン10は収縮した状態にされ、上述の通り、バルーン10とホルダ14の隙間に上行大動脈50が通される。

【0025】そして、コネクタ20側からヘリウムガス 等を給排することにより、心臓の拍動に合わせてバルー ン10が駆動される。なお、このようにバルーン10を 駆動する駆動装置は、IABP等において用いられる駆動装置と全く同様なので、ここでの説明は省略する。

【0026】バルーン10の駆動が開始されると、心臓の拡張期にはバルーン10も拡張さされ、図4(b)に示すように、上行大動脈50を外側から圧迫し、その内部における血圧を高め、冠動脈52への血流量を増大させる。これにより、より多くの酸素が心筋に供給される。一方、心臓の収縮期にはバルーン10も収縮させられ、図4(a)に示すように、上行大動脈50に対する圧迫を緩め、その内部における血圧を低める。その結果、陰圧効果によって左心室54から上行大動脈50への血液の送出抵抗が低下し、左心室54の仕事は軽減される。

【0027】こうして補助循環を実施しながら開胸手術を終える。開胸手術の終了によって患者の胸は閉じられるが、一般的には、術後1~2週間程度は、心機能補助装置1による補助循環を続ける必要があることもあり、心機能補助装置1は患者の体内に留置される。

【0028】その後、患者の容態が回復してくれば、心機能補助装置1が抜去される。この時は、ホルダ14を患者の体内に残したまま、バルーン10およびチューブ12などが患者の体内から引き抜かれる。ホルダ14とバルーン10との接着強度は、チューブ12を引っ張るとホルダ14からバルーン10は、容易に分離することができる。ホルダ14は、人体に悪影響を及ぼすものではなく、体内に留置されても問題はない。

【0029】このように、心機能補助装置1によれば、 開胸手術等が行われる患者に対して補助循環を実施する 場合に、患者の胸部以外に傷をつけなけくてもよくな り、余計な出血も防止されるので、IABPを併用する 場合よりも患者の負担が軽くなる。

【0030】また、心機能補助装置1は、血管の外側に装着されるので、IABPにおいてバルーンカテーテルを血管内へ挿入することによって生じる問題、すなわち、血栓の形成、溶血、下肢の血行障害などといった問題は発生せず、また、仮にバルーン10の破裂を招いたとしても、血管内への駆動流体の混入には至らないので、患者に対する悪影響はほとんどない。

【0031】以上、本発明の実施形態について説明したが、本発明の構成手段については上記実施形態以外にも種々考えられる。例えば、上記心機能補助装置1のホルダ14は、外径形状が直方体となっていたが、より血管を傷つけにくい丸みを帯びた形状となっていてもよい。【0032】また、蓋26がホルダ14に圧入される旨を説明したが、蓋とホルダとが互いの凹凸を係合させるものや、蓋とホルダがヒンジを介して連結されているものなど、具体的な形状については特に限定されない。さらに、ホルダは、上記のように蓋と一体になって環状体を形成するものに限らない。より具体的には、例えば、

図5(a)~同図(c)に示すように、ホルダ40を、柔軟な帯状体41と、帯状体41の一端に設けられたバックル部43とで構成し、帯状体41の他端をバックル部43に通すと、帯状体41が環状になって、バルーン45および上行大動脈50の外周に巻き付く構造としてもよい。このホルダ40において、バックル部43の内側には係合突起47が突設され、一方、帯状体41には長手方向に多数の係合穴49が列設され、帯状体41をバックル部43に通した後、適当な位置で係合突起47を係合穴49に嵌め込むと、ホルダ40を上行大動脈50の外周に巻き付けた状態で固定することができる。このようなホルダ40であれば、帯状体41の締め具合いによって、帯状体41が形成する環の内径を変更することができるので、患者によって上行大動脈50の外径が変わっても、適切に装着することができる。

【0033】また、上記帯状体41を面ファスナによって構成しておけば、バックル部43を設けなくても、環状にして適当な位置で固定することができる。

### 【図面の簡単な説明】

【図1】 実施形態の一例として示した心機能補助装置

の側面図である。

【図2】 ホルダ部分の斜視図である。

【図3】 図1にA-A線で示した切断面端面図であり、(a)はバルーンを拡張した状態、(b)はバルーンを収縮させた状態をそれぞれ示す。

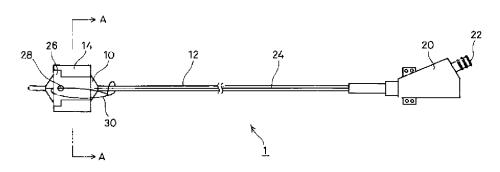
【図4】 心機能補助装置の使用状態を示す模式図であり、(a)は心臓の収縮期の状態、(b)は心臓の拡張期の状態をそれぞれ示す。

【図5】 実施形態の別の例として示した心機能補助装置であり、(a)はその斜視図、(b)はその断面図、(c)はバックル部付近の拡大断面図である。

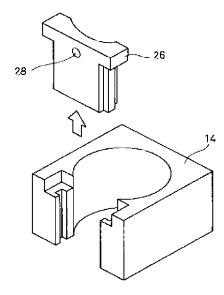
# 【符号の説明】

1・・・心機能補助装置、10・・・バルーン、12・・・チューブ、14・・・ホルダ、20・・・コネクタ、22・・・インデフレーションボート、24・・・ステンレス線、26・・・蓋、28・・・穴、30・・・糸、40・・・ホルダ、41・・・帯状体、43・・・バックル部、45・・・バルーン、47・・・係合突起、49・・・係合穴。

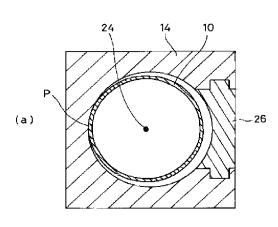
【図1】

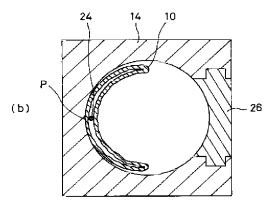


【図2】

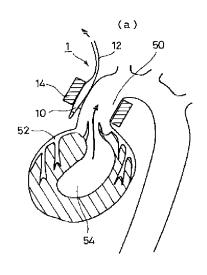


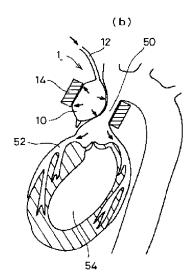
【図3】





【図4】





【図5】

